URGENT DRUG RECALL

Product	*NDC Number*	*Lot*	*Expiration Date*
Vancomycin Hydrochloride for Injection, USP, Equivalent to 1 g Vancomycin (Sterile Powder)	**0409-6533-01**	**43-240-DD**	**1JUL2016**
		44-205-DD	**1AUG2016**
		44-455-DD	**1AUG2016**
		44-460-DD	**1AUG2016**
		44-465-DD	**1AUG2016**

November 7, 2014

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling the lots of Vancomycin Hydrochloride for Injection, USP identified above due to the potential for the tray to be mislabeled as Marcaine™ 0.75% (bupivacaine HCl Injection, USP) as shown in the picture below (Figure 1). There is a potential for therapy to be delayed. Hospira has confirmed one customer report of one tray being mislabeled. The vial labels and shipping container labels are properly marked as Vancomycin Hydrochloride for Injection, USP, Equivalent to 1g Vancomycin (Sterile Powder). The lot number and expiration date on the tray is the same as the vial and shipping container labels and is for Vancomycin Hydrochloride.

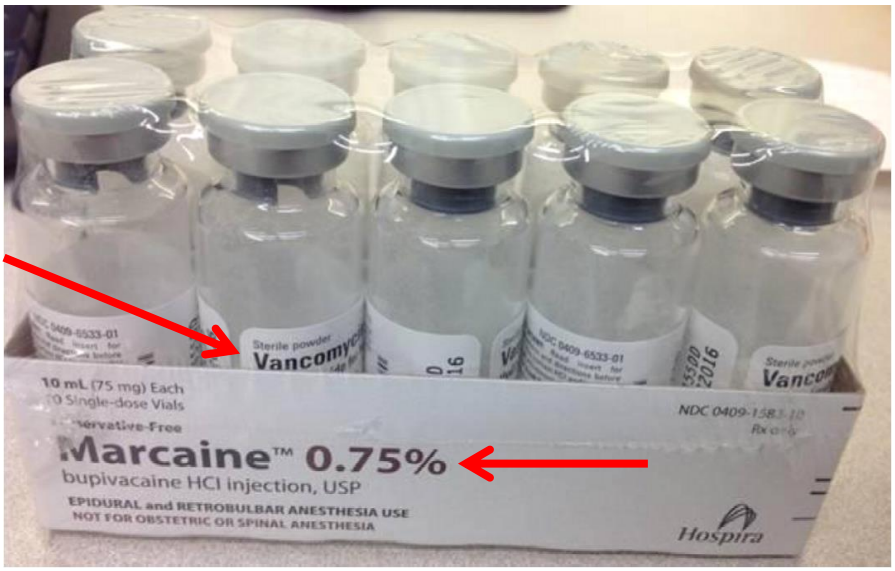

Figure 1

Vancomycin HCl is a white to tan lyophilized powder which requires reconstitution with Sterile Water for Injection. Marcaine HCl is a clear and colorless solution ready for use in a single-dose vial. The likelihood is high that a Healthcare Provider would recognize the incorrect/mismatched container based on the presentation of these two products.

If the wrong solution is selected and administered to a patient, the potential for patient harm can be significant, including hypersensitivity reactions including anaphylactic shock in susceptible patients and/or ototoxicity, nephrotoxicity, DRESS, Stevens Johnson Syndrome, toxic epidermal necrolysis, vasculitis, and agranulocytosis.

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

These lots were distributed September 2014 through October 2014. To date, Hospira has not received reports of any adverse events associated with this issue for these lots.

Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Please check your inventory and immediately stop use and quarantine any affected product. Complete the attached reply form and return it to the fax number or e-mail address on the form, even if you do not have the affected product. Inform healthcare professionals in your organization of this recall.

Return affected product to Stericycle using the label provided with this letter. If you have not received a return label or require additional assistance contact Stericycle at 1-877-270-9244 (M-F, 8am to 5pm ET). To ensure proper and timely credit, follow the instructions on the return label for returning the product. *The return label provided in this notification is for single use only, please DO NOT reproduce.* Please visit http://expertezlabel.com to request additional labels for returning affected product.

This recall is being carried out to the medical facility/retail level (both human and veterinary). Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. If additional copies of the letter and/or reply form are needed, please contact Stericycle at 1-877-270-9244 (M-F, 8am to 5pm ET).

Please contact Hospira Customer Care at 1-877-946-7747 (M-F, 7am to 6pm CT) or your Hospira representative regarding product availability and for questions regarding this field action.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	**Contact Information**	**Areas of Support**
Hospira Global Complaint Management	1-800-441-4100 (M-F, 8am to 5pm CT) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Robert Arnott
Vice President, Quality – US Pharma Operations

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Lake Forest, IL 60045
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Urgent Drug Recall Reply Form – Response Required
Vancomycin Hydrochloride for Injection, USP – Potential for Mislabeled Tray
Lots 43-240-DD, 44-205-DD, 44-455-DD, 44-460-DD, and 44-465-DD
November 7, 2014

Hospira

Check your inventory and complete the information below, even if you do not have the affected product.
Failure to complete all sections of this page may result in improper, delayed or denied credit.

Fax the completed form to 1-877-270-9245 or e-mail the completed form to Hospira7072@stericycle.com.
The return label provided in this notification is for single use only, please DO NOT reproduce. Please visit *http://expertezlabel.com* to request additional labels for returning product. If you have not received a return label or require additional assistance contact Stericycle at 1-877-270-9244 (M-F, 8am to 5pm ET).

Required Information

_____ _____
Business Name Phone Number

_____ _____
Address/City/State/ZIP DEA #

_____ _____
Hospira Customer Number (ship to #) if applicable Your reference # (e.g. PO, Debit Memo or Invoice #)

_____
Completed by: Printed Name/Signature/Date

☐ I have **NO** affected product (fill out and return this form to Stericycle at the fax/e-mail above).

☐ **YES**, I have affected product (fill out and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

If affected product is not being returned, please explain:

- Have you distributed the product further to the medical facility/retail level? YES___ NO___
  - If yes, have you notified your medical facility/retail customers? YES___ NO___ (if no, explain below)

NDC Number	Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, ZIP, quantity from each, and invoice number. If you purchased directly from Hospira leave this section blank.	PO, debit memo or invoice
0409-6533-01				

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